



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1393]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Patent Term Restoration; Due Diligence Petitions; Filing, Format, and Content of Petitions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review - Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0233. The title of this information collection is “Patent Term Restoration; Due Diligence Petitions; Filing, Format, and Content of Petitions.” Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-994-7399, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Patent Term Restoration; Due Diligence Petitions; Filing, Format, and Content of Petitions--21

CFR Part 60

OMB Control Number 0910-0233--Extension

This information collection supports Agency regulations. FDA's patent extension activities are conducted under the authority of section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) and the Generic Animal Drug and Patent Term Restoration Act of 1988 (Pub. L. 100-670) (21 U.S.C. 301, et seq). The regulations are codified in 21 CFR part 60, Patent Term Restoration. New human drug, animal drug, human biological, medical device, food additive, or color additive products regulated by FDA must undergo FDA safety, or safety and effectiveness review before marketing is permitted. If the product is covered by a patent, part of the patent's term may be consumed during this review, which diminishes the value of the patent.

In enacting section 505(j) of the FD&C Act and the Generic Animal Drug and Patent Term Restoration Act of 1988, Congress sought to encourage development of new, safer, and more effective medical and food additive products. It did so by authorizing the U.S. Patent and Trademark Office (USPTO) to extend the patent term by a portion of the time during which FDA's safety and effectiveness review prevented marketing of the product. The length of the patent term extension is generally limited to a maximum of 5 years and is calculated by USPTO based on a statutory formula. When a patent holder submits an application for patent term extension to USPTO, USPTO requests information from FDA, including the length of the regulatory review period for the patented product. If USPTO concludes that the product is eligible for patent term extension, FDA publishes a notice that describes the length of the regulatory review period and the dates used to calculate that period. Interested parties may request, under § 60.24 (21 CFR 60.24), revision of the length of the regulatory review period, or

may petition under § 60.30 (21 CFR 60.30) to reduce the regulatory review period by any time where marketing approval was not pursued with “due diligence.”

In 21 CFR 60.36(a) *due diligence* is defined as “that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.” As provided in § 60.30(c), a due diligence petition “shall set forth sufficient facts, including dates if possible, to merit an investigation by FDA of whether the applicant acted with due diligence.” Upon receipt of a due diligence petition, FDA reviews the petition and evaluates whether any change in the regulatory review period is necessary. If so, the corrected regulatory review period is published in the *Federal Register*. A due diligence petitioner not satisfied with FDA’s decision regarding the petition may request, under § 60.40 (21 CFR 60.40), an informal hearing for reconsideration of the due diligence determination. Petitioners are likely to include persons or organizations having knowledge that FDA’s marketing permission for that product was not actively pursued throughout the regulatory review period. The information collection for which an extension of approval is being sought is the use of the statutorily created due diligence petition.

In the *Federal Register* of August 10, 2022 (87 FR 48667), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

21 CFR Part 60--Patent Term Restoration	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Revision of regulatory review period determinations; § 60.24	4	1.25	5	100	500
Due diligence petitions; § 60.30	1	1	1	50	50
Due diligence hearings; § 60.40	1	1	1	10	10
Total					560

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an overall decrease of 34 hours and 11 responses. Since publication of the 60-day notice, we have adjusted our burden

estimate to reflect an annualized figure (reducing responses associated with § 60.24 by one-third), which results in a decrease to the currently approved burden. There is also a small adjustment decrease of one response associated with submissions received for revision of the regulatory review period determination under § 60.24 since our last review.

Dated: March 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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